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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,292	07/27/2001	Terri L. Butler	374.028US1	8105

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EXAMINER	
FISHER, LATONIA M	
ART UNIT	**PAPER NUMBER**
1623	

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/917,292	Applicant(s) BUTLER ET AL.	
	Examiner La Tonia M. Fisher	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,12 and 16* is/are rejected.

7)☒ Claim(s) *10,13-15 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-17 are pending in application.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

> The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ 2d 1077 (Fed. Cir. 1994). In addition, an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). Lastly, This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required.

The applicant has not specified how the current application is related to US Patent Nos. 6,159,942 and 6,429,198. The applicant must specify the nature of the relationship between the applications. Here, while the applicant's references the US Provisional Application titled "*Compositions for Enhancing Physical Rehabilitation in Humans and Method of Using the Same*," filed June 29, 2001, the applicant did not provide the serial number of the provisional

application. In order to show relation to and claim the priority date of a provisional application, the applicant must provide the serial number of such application so that the examiner may determine the proper priority status.

Furthermore, the provisional applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-3, 11 and 12 of this application. Specifically, the provisional applications cited do not indicate the corresponding amounts of ribose that should be administered, the number of times the ribose is administered daily, the specific vasodilators intended for use, or the corresponding amounts of vitamins that should be administered.

It is noted that the provisional applications cited do provide adequate support for Claims 4-9 and 16 in the following manner: Provisional Application No. 60221526, filed July 28, 2000, provides support under 35 U.S.C. 112 for Claims 4-9. Provisional Application No. 60/302200, filed June 29, 2001, provides support under 35 U.S.C. 112 for claim Claim16.

Claim Objections

Claims 10, 13-15 and 17 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 10, 13-15 and 17 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. Particularly, the wording "administering" in Claim 4 is ambiguous. There, Applicant states, " A composition for improving cardiovascular function of a subject comprising administering ..." It is unclear from the language of Claim 4 whether the applicant is identifying a method or a composition. Accordingly, since Claims 5-9 depend on Claim 4, these Claims are also rejected.

Claim11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Here, the applicant does not indicate the particular vitamin intended for the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4-7 and 9 rejected under 35 U.S.C. 102(b) as being anticipated by Cotter et al. (USPN 4,920,098).

Claims 4-7 and 9 are drawn to compositions comprising D-ribose and a vasodilator. Cotter et al. teaches a method for providing cardiovascular therapy by administering ribose, L-arginine and L-carnitine to a subject (USPN '098, Col. 12, lines 7-12, Claim 11). Thus, Cotter et al. teaches and suggests every element of Claims 4-7 and 9 which encompasses administering ribose with a vasodilator. This disclosure anticipates the compositions instantly claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 9 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotter et al. (USPN 4,920,098) in view of Foker (USPN 4,719,201).

Claims 1-3, 9 and 16 are drawn to compositions comprising D-ribose and methods for improving cardiac and cardiovascular function of a subject comprising administration of said composition. The present invention is also directed to the treatment of hypertension, an art recognized symptom of congestive heart failure.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Cotter et al. teaches a method for providing cardiac and cardiovascular therapy by administering ribose, L-arginine and L-carnitine to a subject (USPN '098, Col. 10, lines 46-51, Claim 3 and Col. 12, lines7-12, Claim 11). Cotter et al. also discloses that patients suffering from congestive heart failure are typically, underweight with poor nutritional status. Cotter et al. teaches that hypertension is a result of protein-calorie malnutrition. (USPN '098, Col. 1, lines 38-44, 52-53; *See also* USPN '098 Col. 9, lines 33-37).

Cotter et al. does not teach compositions comprising D-ribose. Cotter et al. also does not teach administration of the ribose one to four times daily. However, Cotter et al. teaches a supplement comprising ribose. One skilled in the art would recognize that supplements are synonymous with taking/administering a composition at least one to three times a day with meals.

Foker teaches a method for reducing the recovery time of tissue function following ischemic insult due to myocardial infarction, well known in the art as a predisposing factor for congestive heart failure, by administering a composition of D-ribose. (USPN '201, Col. 10, lines, 28-52, Claims 3 and 4 and Col. 11, lines 4-41, Claims 10 and 11).

It would have been obvious for a person of ordinary skill in the art at the time of the claimed invention to administer D-ribose as the ribose source to a patient with congestive heart failure and/or factors directly related to a cardiac disorder and the motivation is provided in the

prior art disclosure since the prior art discloses and suggests the effectiveness of D-ribose when administered as an active agent to facilitate cardiac therapy.

Claims 8, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotter et al. (USPN 4,920,098) in view of each of Foker (USPN 4,719,201) and Wakat (USPN 6,054, 128).

Claim 8 is drawn to a composition for improving cardiovascular function comprising D-ribose, a vasodilator and at least one of glucose, glutamine, Vitamins C, B6, and B12, and folic acid.

Claims 11 and 12 are drawn to compositions for improving cardiac function comprising D-ribose, glucose, L-arginine, Vitamin C, Vitamin B12 and Vitamin B6.

As discussed above, Cotter et al. teaches a method for improving cardiac and cardiovascular function by administering ribose, L-cartinine, glucose and L-arginine to a subject. (USPN '098, Col. 10, lines 46-51, Claim 3 and Col. 12, lines7-12, Claim 11). Cotter et al., does not teach compositions comprising D-ribose, folic acid or vitamins C, B6 and B12. Lastly, Cotter et al. also does not teach administration of the ribose one to four times daily. However, Cotter et al. teaches a supplement comprising ribose. One skilled in the art would recognize that supplements are synonymous with taking/administering a composition at least one to three times a day with meals.

Foker teaches a method for reducing the recovery time of tissue function following ischemic insult due to myocardial infarction, well known in the art as a predisposing factor for congestive heart failure, by administering a composition of D-ribose. (USPN '201, Col. 8, 5-60. Claims 3 and 4).

It would have been obvious for a person of ordinary skill in the art at the time of the claimed invention to administer D-ribose as the ribose source to a patient with congestive heart failure and/or factors directly related to a cardiac disorder and the motivation is provided in the prior art disclosure since the prior art discloses and suggests the effectiveness of D-ribose when administered as an active agent to facilitate cardiac therapy.

Wakat discloses a method for preventing or lessening the risk of cardiovascular associated diseases and health conditions by orally administering a composition comprising of folic acid and vitamins, B6, B12 and C. ('128, Col.8, lines 50-55; Col. 9, lines 62-67, Col. 10, lines 1-27, Claims 1 and 2; Col. 11, lines 4-41, Claims 10 and 11).

It would have been obvious for a person of ordinary skill in the art at the time the claimed invention was made to combine folic acid, and vitamins C, B6, and B12, all recognized as active agents for treating related cardiac disorders and diseases, into a single composition for treating cardiac disorders and diseases as Applicants have done with the above cited references before them. It requires little more than routine skill in the art to combine art recognized active agents for treating congestive heart failure and related symptoms since the art discloses these components in combination. *See* In Re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (C.C.P.A. 1980) (It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose.)

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to La Tonia M. Fisher whose telephone number is (703) 306-5819. The examiner can normally be reached on Monday - Friday from 9:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (703) 308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

LMF
November 21, 2002

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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